

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	CRIMINAL NUMBER 04-443
SCHERING SALES CORP.	:	

GOVERNMENT’S PLEA MEMORANDUM

The defendant will plead guilty to the single charge in the Information, a violation of the anti-kickback statute, 42 U.S.C. § 1320a-7b(b)(2)(B). This memorandum is submitted to the Court to outline the elements of the offense, the penalty and the plea agreement and to give a factual basis to support the plea. The plea agreement is filed with this Memorandum.

I. ELEMENTS OF THE OFFENSE

The elements of 42 U.S.C. § 1320a-7b(b)(2)(B) are as follows:

1. It is an offense for any person knowingly and willfully
2. to offer or pay
3. any remuneration (including any kickback, bribe, or rebate)
4. directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person

...

- b. to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

The statute makes the payment of “any remuneration” to get business a crime. In *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985), the court held that this covered not only payments for which nothing was done, but even payments for services which were performed, as long as one of the motivations for the payment was to get business. The court wrote:

The text refers to “any remuneration.” That includes not only sums for which no actual service was performed, but also those amounts for which some professional time was expended. “Remunerates” is defined as “to pay an equivalent for service.” Webster Third New International Dictionary (1966). By including such items as kickbacks and bribes, the statute expands “remuneration” to cover situations where no service is performed. That a particular payment was a remuneration (which implies that service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.

Thus, it does not matter if the defendant had multiple purposes for making the payments, some legitimate and some criminal. “[I]f one purpose of the payment was to induce referrals, the Medicare statute has been violated.” *Id.* at 69.

II. MAXIMUM PENALTY

The maximum penalty is five years probation and a fine of twice the gross gain to the defendant. 18 U.S.C. § 3571(d). In this case the maximum fine is \$92 million.

III. THE PLEA AGREEMENT

The plea agreement with Schering Sales Corporation (hereafter “Schering Sales”), the defendant in this case, is related to a civil settlement with its parent corporation, Schering-Plough Corporation. The plea agreement is made under Rule 11(c)(1)(C), Fed.R.Crim.P. Under that rule, if the Court does not accept the plea agreement, the defendant may withdraw its plea.

Under the plea agreement, Schering Sales Corporation will plead guilty to the Information and agrees to a sentence of a fine of \$52.5 million. Because under the separate civil

settlement agreement, Schering-Plough Corporation will pay \$292,969,482.00 to make whole the various public health programs that were defrauded in this scheme, the parties have agreed that the Court should not enter a restitution order as part of the criminal sentence. Schering Sales agrees to pay the fine within one week of the imposition of sentence and to pay the \$400 special assessment on the date of sentencing. Because Schering Sales will be excluded from participation in government health care programs and because Schering-Plough Corporation has entered into a corporate integrity agreement with the Department of Health and Human Services, the parties agree that there is no need for the Court to impose a term of probation.

The parties will ask the Court to impose sentence as soon as the guilty plea is entered.

The plea agreement and the separate agreement with Schering-Plough Corporation contain a non-prosecution agreement under which the United States agrees that it will not charge either Schering Sales Corporation or Schering-Plough Corporation with other crimes that were within the scope of the investigation conducted by the United States Attorney's Office for the Eastern District of Pennsylvania. There are certain exceptions to the non-prosecution agreements that are detailed within the agreements.

Finally, the defendant waives its right of appeal.

IV. STATEMENT OF FACTS IN SUPPORT OF THE GUILTY PLEA

Claritin was the flagship product of the Schering corporate family. The Health Maintenance Organization (HMO) maintained a formulary for pharmaceutical products. A formulary is a list of approved drugs in particular therapeutic classes that an HMO agrees to pay for if prescribed by a physician for its health plan members.

During 1997, Schering Sales and the HMO entered into agreements to govern the price of the Schering drugs that the HMO made available to its enrollees through its health plan formularies, including the Claritin family of products. Each agreement had a term of three years.

Maintaining this relationship with the HMO was important to Schering Sales. Each year, the HMO's enrollees utilized more than \$100 million worth of the Schering drugs included on the HMO health plan formularies, with Claritin comprising a larger portion of that utilization than any other single drug.

In 1998, less than one year into the 1997 agreements' three-year term, the HMO began voicing concerns that the manufacturer's direct-to-consumer advertising had resulted in higher utilization of Claritin than it had projected and therefore also higher costs. The HMO also complained that the price it was paying for Claritin was substantially higher than the price it was paying for Allegra. The HMO asked Schering Sales to decrease the effective Claritin price (by increasing the Claritin discounts and rebates it was providing to the HMO) to meet Allegra's price.

Schering Sales refused to decrease the Claritin price. As a result, in September 1998, the HMO's Pharmacy and Therapeutics ("P&T") Committee voted to remove Claritin from the HMO's formulary. Upon learning of the vote, Schering Sales discussed with the HMO what it would take financially for the HMO's senior management to reject the P&T Committee's recommendation. The HMO told Schering Sales that it would need to "bring [its Claritin tablet] price down to Allegra" in order to avoid having it removed from formulary. Schering Sales

calculated the amount the HMO would save if it used Allegra rather than Claritin and offered to make up the difference.

Schering Sales was aware that providing the HMO with a lower Claritin price would have required Schering Sales to report lower Claritin Best Prices to the government, resulting in lower Medicaid prices for Claritin (through increased rebates going to Medicaid). To avoid lowering the Claritin price, Schering Sales ultimately provided the HMO with a \$10 million package of other types of payments and services that was specifically tailored to lower the HMO's effective price for Claritin without correspondingly lowering the Medicaid price.

As part of this deal, Schering Sales agreed to make annual cash payments to the HMO of approximately \$2.5 million that were described as a "data fee." These payments were ostensibly in exchange for the HMO's agreement to provide Schering with annual reports containing detailed, regional utilization data. In reality, however, under the 1997 agreements, the HMO was already required to provide (and had been providing) Schering Sales with the same detailed, regional data quarterly for purposes of calculating Schering's rebate payments to the HMO. The annual report was merely a cumulation of the quarterly reports. The annual reports were therefore of no practical value to Schering Sales. The primary purpose of the data fee payment to the HMO was to keep Claritin on the HMO's formulary.

One annual report was in fact delivered. The report was in a format that Schering Sales could not easily access; Schering Sales never used this data. Nevertheless, Schering Sales paid the fee to the HMO. Because the first payment was for three-quarters of a year, the amount paid was \$1,831,968.99.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of the Government's Plea Memorandum upon the following by e-mail on August 10, 2004:

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August 12, 2004